

AUG 9 1994

Philips' BV Laser Alignment Tool
510(k) Summary

K943381

General Information

Trade Name

Laser Alignment Tool

Classif Name

Light Beam Patient Position Indicator
Class II 21 CFR 892.5780 (90 IWE)

Perf. Standards

IEC 825 Rad. Safety of Laser Prod.
IEC 601.1 Elect Safety of Med Equip
UL 187 X-Ray Equip Safety Std.
21CFR1040.10 Laser Prod Perf Std

Reason for 510K : Philips Medical Systems intends to manufacture and market a laser patient positioning tool for the BV series of mobile fluoroscopy systems. This will be a new Philips accessory for these systems. It is substantially equivalent to a similar device manufactured by TRAC Medical Inc. and currently legally marketed by Philips as an accessory for the BV systems. Intended uses and all other aspects are identical with the exception of the method of mounting the device and, subsequently, the method of initially aligning it

Predicate Device :

Orthotrac Coaxial Laser
TRAC Medical Systems
K933431 - 05 Oct. 1993

Intended Use Statement: The laser alignment tool is used for patient positioning on our BV series Mobile Fluoroscopic X-Ray Systems. The current procedure is to use fluoroscopic x-ray exposure to correctly position the patient relative to the central x-ray beam. By providing a visible indicator of the central beam location, patient positioning is facilitated for the surgeon while x-ray dose is reduced for the patient. Clinical applications include situations in which the surgeon utilized the x-ray beam for alignment or guidance in a procedure. The procedures themselves would not be altered with the exception of the use of the visible spectrum to indicate alignment rather than fluoroscopic shadows. The system consists of a HeNe laser device and an optical guide which allows the light to be emitted long the central axis of the x-ray beam. A means is provided to physically align the beam. The laser alignment tool is an accessory used to visualize the location of the central axis of the x-ray beam whether or not x-rays are energized. It has no clinical value beyond the surgeon's use of that visualization. It does not enable new treatments nor generate information which is not available through other means. The accuracy of the visualization is wholly demonstrable through the use of bench testing and specification.

Comparison to Predicate: The Philips Laser Alignment Tool utilizes the identical principals and similar materials to accomplish an identical objective as the ORTHOTRAC Coaxial Laser; i.e., to project an optical marker along the central axis of the fluoroscopic x-ray beam. The Philips system differs from the TRAC system in two ways. The laser source has been placed on the tube side of the imaging system as opposed to the I.I. side. This is done to remove any harsh shadow the device may create on the image and preclude the necessity of making the device removable in order to retain application flexibility desirable in a mobile system.

Manufacturer : Philips Medical Systems Nederland B.V.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

Timothy W. Capehart
Senior Regulatory Affairs Spec.
Philips Medical Systems
710 Bridgeport Avenue
Shelton, Connecticut 06484

Re: K943381
Laser Alignment Tool (LAT)
Dated: July 8, 1994
Received: July 13, 1994
Regulatory Class: II
21 CFR 892.5780/Procode: 90 IWE

Dear Mr. Capehart:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-300) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health